
MEMORANDUM

TO: VERMONT HOSPITAL CHIEF EXECUTIVES, HOSPITAL QUALITY IMPROVEMENT OFFICERS, AND OTHER INTERESTED PERSONS

FROM: SHARON MOFFATT, RN, MSN, ACTING COMMISSIONER OF HEALTH

DATE: DECEMBER 11, 2006

RE: INTERIM GUIDANCE FOR HOSPITALS: NEW REPORTING REQUIREMENTS FOR "INTENTIONAL UNSAFE ACTS"

In 2006, the Vermont legislature created a new "Patient Safety Surveillance and Improvement System" to be administered by the Department of Health. Most of the new provisions, at Chapter 43A of Title 18, do not go into effect until after the Health Department adopts Patient Safety rules to implement the law. The Health Department will be inviting public comment during the rulemaking process in early 2007. Information about opportunities to provide input will be published in newspapers of record as part of the rulemaking process and also will be posted at <http://healthvermont.gov/events.aspx>.

However, one section of the Act went into effect on July 1, 2006. Section 1916 relating to *Intentional Unsafe Acts* requires hospitals to notify the Health Department whenever information available to them supports a reasonable, good faith belief that an Intentional Unsafe Act has occurred.

Pending adoption of the Patient Safety rules, the Health Department is providing this interim guidance memorandum to assist hospitals in understanding their current obligations to report Intentional Unsafe Acts.

We encourage your active participation in the rulemaking process and your questions and comments concerning this interim guidance. Please contact Tricia Cummings, Director of the Health Department's Patient Safety Program at (802) 951-1224 with any questions.

**VERMONT DEPARTMENT OF HEALTH
INTERIM GUIDANCE FOR HOSPITALS:
NEW REPORTING REQUIREMENTS FOR "INTENTIONAL UNSAFE ACTS"**

Beginning on July 1, 2006, Vermont hospitals are required to report to the Department of Health whenever information available to them supports a reasonable, good faith belief that an “Intentional Unsafe Act” has occurred.¹ This reporting requirement is part of the new “Patient Safety Surveillance and Improvement System.”² In 2007, the Vermont Department of Health will promulgate rules to implement this new law. Pending adoption of the Patient Safety rules, the Health Department is providing this interim guidance to assist hospitals in understanding their current obligations to report Intentional Unsafe Acts to the Health Department’s Patient Safety Program as required by the new law.

The law defines *Intentional Unsafe Act*³ to mean an *adverse event*⁴ or *near miss*⁵ that results from:

- (A) a criminal act;
- (B) a purposefully unsafe act;
- (C) alcohol or substance abuse; or
- (D) patient abuse.

A complete copy of the Patient Safety Surveillance and Improvement System Act is attached. The Act also is available at:

<http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/acts/ACT215.HTM> (Sections 323 through 326 of Act 215).

¹ 18 V.S.A. § 1916(a): “A hospital shall notify the department, within the time frames established by regulation, if the information available supports a reasonable, good faith belief that an intentional unsafe act as it pertains to patients has occurred.”

² The new law was enacted in Act 215 of the 2005-2006 Legislative Session, Sections 323 through 326, amending 1 V.S.A. § 317(c), 18 V.S.A. § 1905, 26 V.S.A. § 1443 and creating a new Chapter 43A of Title 18 (§§ 1912-1919).

³ 18 V.S.A. § 1912(6).

⁴ 18 V.S.A. § 1912(1): “‘Adverse event’ is any untoward incident, therapeutic misadventure, iatrogenic injury, or other undesirable occurrence directly associated with care or services provided by a health care provider or health care facility.”

⁵ 18 V.S.A. § (7): “‘Near miss’ means any process variation that did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome.”

I. What to Report:

A hospital must report Intentional Unsafe Acts to the Patient Safety Program whenever the information available supports a reasonable, good faith belief that **ALL (not just some)** of the following criteria are present:

- ☐ There was an adverse event or near miss directly associated with patient care or services **AND**
- ☐ The adverse event or near miss affected or could have affected a patient or patients **AND**
- ☐ The adverse event or near miss resulted from acts or omissions by a health care provider, employee, volunteer or individual credentialed by a health care facility **AND** meets **one or more of the following**:

- 1. The acts or omissions may be a violation of criminal law.**
 - There may have been intent to harm; **OR**
 - There is a reasonable good faith belief that a criminal act has occurred; **OR**
 - The hospital has reported the act or omission to law enforcement authorities.
- 2. The acts or omissions were purposefully unsafe.**
 - There was a conscious act or omission or reckless behavior; **AND**
 - The adverse event or near miss did not happen as a result of understandable accident or inadvertence; **AND**
 - No reasonable person with similar qualifications, training and experience would have acted the same way under similar circumstances; **AND**
 - There were no extenuating circumstances that could justify the acts or omissions.
- 3. The acts or omissions took place while the individual involved was under the influence of alcohol or other substances.**
- 4. The acts or omissions were of a type or nature that Vermont law makes reportable as abuse, neglect or exploitation to:**
 - Adult Protective Services or
 - Department of Children and Families in the case of a child.

II. When to Report:

- A hospital must report to the Patient Safety Program as soon as reasonably and practically possible, but no later than seven (7) days after the discovery or recognition of the Intentional Unsafe Act.

- Securing the health and safety of patients and others in the hospital should always be the first priority.
- If there is an existing mandate to make a prompt report to another agency or if there is another legal authority that should be contacted immediately in order to protect and secure health and safety, that should be done first.

III. How to Report:

A hospital report must be submitted to the Health Department's Patient Safety Program by calling or writing to:

Tricia Cummings, Director
Patient Safety Program
Vermont Department of Health
108 Cherry Street, Box 70,
Burlington, Vermont, 05402
Phone Number: (802) 951-1224
Fax Number: (802) 951-1275

If submitting the report by mail or fax, please mark the envelope or fax cover page:
"URGENT: PATIENT SAFETY PROGRAM - CONFIDENTIAL"

If Ms. Cummings is not available to take a telephone call, the caller should ask for the person assigned to cover the Patient Safety Program.

IV. Specific Considerations:

- 1. A hospital must report an Intentional Unsafe Act to the Patient Safety Program regardless of whether it will also examine the adverse event or near miss through its risk manager, peer review committee or other departments within the hospital.**
 - *The hospital's internal policies or procedures or peer review may not prevent, delay or interfere with timely reporting to the Patient Safety Program.*
 - The hospital must make a reasonable effort to obtain the facts. When the information available supports a reasonable, good faith belief that the act meets all the criteria to be considered an Intentional Unsafe Act, then the adverse event or near miss must be reported to the Patient Safety Program.

- The law does not prevent the hospital from conducting its own further investigation or peer review.
- 2. A hospital must not delay reporting to the Patient Safety Program until the hospital decides whether the individual(s) involved will be disciplined.**
- *The Patient Safety Program report may not be deferred or delayed to await the determination of whether the hospital will take disciplinary action.*
 - The reporting obligation under these provisions commences at the time the information available to the hospital after making reasonable efforts to obtain all the facts supports a reasonable, good faith belief that an Intentional Unsafe Act as it pertains to a patient or patients has occurred.
 - Whenever the information available supports such a belief, the hospital must make a report to the Patient Safety Program.
- 3. Certain adverse events or near misses that must be reported to the Patient Safety Program may also require a hospital to report to another state or federal government agency.**
- *The Health Department will work with hospitals to minimize the need to duplicate effort, but the new Patient Safety reporting requirements cannot and do not replace or limit the need to fully comply with other laws.*
 - Dual reporting is required when an event that is reportable under another provision of law also meets all of the criteria for an Intentional Unsafe Act.
 - If an adverse event or near miss that is reportable to the Patient Safety program as an Intentional Unsafe Act has been reported in writing to another state or federal government agency, a copy of the hospital's written report to the other agency may be used as its written Patient Safety Program report, if the other law permits.

V. Additional Provisions of the Law:

1. VDH Obligations Regarding Reports of Intentional Unsafe Acts

The Department of Health's Patient Safety Program will review all Intentional Unsafe Act reports. If the Department confirms or independently concludes, based on a reasonable good faith belief that an Intentional Unsafe Act has occurred, it is required to notify relevant state and federal licensing and other regulatory entities, and in the case of possible criminal activity, relevant state and federal law enforcement authorities. The Department's Patient Safety Program will notify relevant authorities, including those within the Department itself, only after confirming or independently concluding an Intentional Unsafe Act has occurred, as required by this law.

2. Immunity

If an individual or hospital takes action to report what is believed in good faith to be an Intentional Unsafe Act, and it acts without malice and with a reasonable belief that the action is warranted based on reasonable efforts to obtain all of the facts, there shall be no liability for such action or cause of action for damages.

3. Hospital Investigation or Peer Review Not Restricted

The law imposes new reporting obligations and does not prevent a hospital from conducting its own investigation or peer review. As noted above, any hospital investigation or peer review may not delay the fulfillment of the reporting obligations imposed by this law.

VI. Additional Background Information

The source of the concept and language for Intentional Unsafe Acts provisions in the new law was the policy followed by the National Center for Patient Safety of the Veteran's Administration. (See <http://www.patientsafety.gov/vision.html#approach> and <http://www.patientsafety.gov/CogAids/Triage/index.html>)

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